## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Shelby L. Cook et al.

Application No. 10/615,625

Filed: June 27, 2003

For: BIOABSORBABLE SUTURE ANCHOR SYSTEM FOR USE IN SMALL JOINTS

o. 10/615,625 Art Unit: 3731

Examiner: Tuan Van Nguyen

Confirmation No. 9377

I hereby certify that this correspondence is being sent via EFS-Web to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-

1450, on the date shown below.

Dated:

September 2, 2009

Signature:

(Rory P. Pheiffer)

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## <u>Declaration of Shelby L. Cook, Jose E. Lizardi, Karl S. Reese, and Thomas A. Shepard</u> <u>Pursuant to 37 C.F.R. § 1.131</u>

Dear Sir:

We, Shelby L. Cook, residing at 33 Fairway Lane, Foxboro, MA 02035, Jose E. Lizardi, residing at 3 Kayla Drive, Franklin, MA 02038, Karl S. Reese, residing at 764 Tremont Street, #5 Boston, MA 02118, and Thomas A. Shepard, residing at 5250 Greens Dairy Road, Raleigh, NC 27616, hereby declare as follows:

1. As co-inventors of the subject matter claimed in this patent application, we are familiar with the patent application and its claims, as well as the development of the claimed invention. We understand that an Office Action mailed March 30, 2009, rejects claims 1, 8, 9-13, 15, 16, and 19 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,320,701 of Haut et al. ("the Haut patent"), and furthermore, rejects claims 2, 3, 14, 17, and 18 pursuant to 35 U.S.C. §103(a) as being obvious over the Haut patent.

2. We understand that the Haut patent has a §102(e) date of June 2, 2003 (based on its filing date). We believe that the facts set forth below evidence that the invention claimed in this patent application was at least conceived prior to June 2, 2003, which is the earliest priority date that could possibly be claimed by the Haut patent.

- Before June 2, 2003, at least two pages of drawings of the claimed invention were 3. prepared, a redacted copy of which is attached hereto as Exhibit A. These drawings, which are dated (redacted) prior to June 2, 2003, illustrate the details of the invention as claimed in the independent claims, thus showing conception of the invention. In particular, the drawings illustrate a suture anchor for anchoring tissue to bone that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in a suture channel of the anchor. An elongate body defined by a longitudinal axis of symmetry and having a first, leading end and a second, trailing end is illustrated at least in Figures A, Sections A-A, and the perspective views of pages 1 and 2, and Figure B of page 2. Two opposed surfaces between the first and second ends and a plurality of sidewalls extending between the two opposed surfaces is illustrated at least in the Figures A and the perspective views of pages 1 and 2. Figures A and the perspective views of pages 1 and 2 also illustrate a flared portion formed on the second end and extending from one of the sidewalls. The flared portion is adapted to engage and anchor into bone tissue. A suture channel formed in the elongate body for passage of a suture strand therethrough and extending between the two opposed surfaces is illustrated at least in Section A-A of page 1 and Section A-A and Figure B of page 2. As shown, the suture channel is oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and as shown in Figures A of pages 1 and 2, a centerline of the suture channel is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion.
- 4. We were reasonably diligent in constructively reducing our invention to practice by filing a patent application on June 27, 2003, which is less than one month after the earliest priority date that could possibly be claimed by the Haut patent.
- 5. All of these acts relating to the conception and completion of this invention took place in the United States.
- 6. We further declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| Date: 14 Aug -2009 |                   |
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| <b>O</b>           | Shelby L. Cook    |
| Date:              | Jose E. Lizardi   |
| Date:              | Karl S. Reese     |
| Date:              | Thomas A. Shepard |

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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|                | Karl S. Reese     |
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| Date: 8/19/09 | 1560              |
| •             | Thomas A. Shepard |